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September 8, 2022

The Honorable Colm F. Connolly
United States District Court
844 N. King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *BIAL - PORTELA & CA S.A. et al. v. Alkem Labs. Ltd.,*
C.A. Nos. 18-304-CFC-CJB, 20-786-CFC-CJB, and 21-186-CFC

Dear Chief Judge Connolly:

In accordance with the Court's September 6 Oral Order, Plaintiffs write to explain BIAL - HOLDING, S.A.'s ("Bial Holding") connection with the above-captioned actions.

Bial Holding is a privately held Portuguese corporation. *See* Trial Tr. 51:10 (Duffy) ("Bial is a small family-owned pharmaceutical company."). Bial Holding is the parent company of BIAL - PORTELA & CA S.A. ("Bial Portela"), the assignee of the patents in suit. *See, e.g.,* C.A. No. 18-304-CFC-CJB, D.I. 1, ¶ 2; D.I. 6, ¶ 1; D.I. 235-1 at Ex. 1, ¶¶ 17, 26, 36, 47, 58. As Bial Portela's parent company, Bial Holding oversees Bial Portela's intellectual property strategy and licensing activities, including those related to the patents in suit. Further demonstrating its interest, Bial Holding, along with Bial Portela, has stipulated to multiple dismissals of actions with other defendants relating to the patents in suit due to settlement agreements. *See, e.g.,* C.A. No. 18-341-CFC-CJB, D.I. 193; C.A. No. 18-342-CFC-CJB, D.I. 135; C.A. No. 18-336-CFC-CJB, D.I. 196; C.A. No. 18-312-CFC-CJB, D.I. 158; C.A. No. 18-775-CFC-CJB, D.I. 122; D.I. 18-279-CFC-CJB, D.I. 200. Bial Holding, therefore, has an equitable interest in the patents in suit and has standing to bring these actions. *See Hologic v. Minerva Surgical, Inc.*, 163 F. Supp. 3d 118, 122 (D. Del. 2016) (finding parent company could sue for injunctive relief because it had established equitable standing).

Accordingly, and importantly, Alkem has not contested that Bial Holding is a proper party in these actions, which is why Plaintiffs did not use trial time to introduce evidence with respect to this uncontested issue. *See* C.A. No. 18-304-CFC-CJB,

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D.I. 235, ¶ 26 (“Otherwise, no party contests Plaintiffs’ standing for purposes of these actions, and the parties agree that no proof of standing needs to be adduced at trial.”); D.I. 235-1 at Ex. 1, ¶ 15 (Joint Statement of Uncontested Facts) (“Alkem does not contest that Plaintiffs have standing to bring these actions for alleged infringement of the patents-in-suit.”); *see also* D.I. 261, ¶ 19 ([Corrected] Plaintiffs’ Proposed Findings of Fact on Infringement). Each of Plaintiffs’ complaints in these actions alleges that Plaintiff “BIAL - HOLDING, S.A. is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão e São Mamede) 4745-365 Trofa, Portugal.” *See* C.A. No. 18-304-CFC-CJB, D.I. 1, ¶ 2; C.A. No. 20-786-CFC-CJB, D.I. 6, ¶ 2; C.A. No. 21-186-CFC, D.I. 1, ¶ 2.¹ Further, Plaintiffs’ Federal Rule of Civil Procedure 7.1 Disclosure Statement for each action lists Bial Holding as the “parent corporation of BIAL - PORTELA & CA S.A.” *See* C.A. No. 18-304-CFC-CJB, D.I. 6, ¶ 1; C.A. No. 20-786-CFC-CJB, D.I. 5, ¶ 1; C.A. No. 21-186-CFC, D.I. 5, ¶ 1.

Alkem also did not contest Bial Holding’s standing or status as Bial Portela’s parent company in its answers or counterclaims for noninfringement and invalidity filed in 2018, 2020, or 2021, or throughout the case. *See* C.A. No. 18-304-CFC-CJB, D.I. 13, ¶ 12 (Alkem’s Counterclaims). Indeed, Alkem’s counterclaims affirmatively concede that each Plaintiff, including Bial Holding, has standing in these actions, stating that “[a] definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Alkem and Counterclaim Defendants [defined as Bial Portela, Bial Holding, and Sunovion Pharmaceuticals Inc.] regarding the infringement [or validity] of the [patents in suit].” *See* C.A. No. 18-304-CFC-CJB, D.I. 13, ¶¶ 24, 29, 34, 39, 44, 49, 54, 59, 64, 69, 74, 79 (Alkem’s Counterclaims); C.A. No. 20-786-CFC-CJB, D.I. 11, ¶¶ 17, 22, 27, 32, 37, 42 (Alkem’s Counterclaims); C.A. No. 21-186-CFC, ¶ 17, 22 (Alkem’s Counterclaims).

Counsel are available should the Court have any further questions.

¹ Plaintiffs’ complaints also name BIAL - PORTELA & CA S.A. (the owner of the patents in suit) and Sunovion Pharmaceuticals Inc. (the NDA holder and an exclusive licensee of the patents in suit in the United States) as plaintiffs in these actions. *See* C.A. No. 18-304-CFC-CJB, D.I. 1, ¶¶ 1, 4, 30, 36, 39, 42, 45, 48, 51; C.A. No. 20-786-CFC-CJB, D.I. 1, ¶¶ 1, 4, 34, 40, 46, 52; C.A. No. 21-186-CFC, D.I. 1, ¶¶ 1, 4, 35, 41.

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Respectfully,

/s/ Steven J. Balick

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SJB/nlm

cc: All counsel of record (via electronic mail)